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Of Counsel for Plaintiff Horizon Therapeutics, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON THERAPEUTICS, INC.,

Plaintiff,

v.

PAR PHARMACEUTICAL, INC.,

Defendant.

Civil Action No. 1:16-cv-_____

COMPLAINT

Plaintiff Horizon Therapeutics, Inc., by its undersigned attorneys, brings this action against Defendant Par Pharmaceutical, Inc. ("Defendant" or "Par"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiff's pharmaceutical product RAVICTI® (glycerol phenylbutyrate) ("RAVICTI®") prior to the expiration of United States Patent Nos. 9,095,559 ("the '559 patent"), 9,254,278 ("the '278 patent"), and 9,326,966 ("the '966 patent").

THE PARTIES

2. Plaintiff Horizon Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 150 S. Saunders Road, Lake Forest, IL 60045.

3. On information and belief, Defendant Par Pharmaceutical, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Ram Ridge Rd, Chestnut Ridge, NY 10977.

4. On information and belief, Par is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

5. On information and belief, Par is registered to do business in the State of New Jersey under Business ID Number 0100071541 and is registered as a manufacturer and wholesale distributor of drugs in the State of New Jersey under Registration Number 5004032.

6. Par has filed Abbreviated New Drug Application ("ANDA") No. 205742 ("the Par ANDA") with the Food and Drug Administration ("FDA") seeking approval to market and sell a generic version of RAVICTI® (glycerol phenylbutyrate oral liquid) ("the Par Product") throughout the United States, including in New Jersey.

7. On information and belief, Par has availed itself of the rights, benefits and privileges of this Court by filing at least one complaint for patent infringement in the District of New Jersey: *Par Pharmaceutical, Inc. and Par Sterile Products, LLC v. Luitpold Pharmaceuticals, Inc., Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd*., Civil Action No. 2:16-cv-02290.

8. On information and belief, Par has admitted to, consented to or has not contested, the jurisdiction of this Court in at least one prior District of New Jersey action: *Merck Sharp & Dohme Corp. v. Par Sterile Products, LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical Holdings, Inc*., Civil Action No. 3:16-cv-00948; *Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited v. Par Pharmaceutical, Inc.,* Civil Action No. 2:15-cv-07580; and *Alcon Pharmaceuticals, Ltd., Alcon Laboratories, Inc., and Alcon Research, Ltd. v. Par Pharmaceutical, Inc*., 3:15-cv-07240.

9. On information and belief, Par has availed itself of the rights, benefits and privileges of this Court by asserting counterclaims in at least three prior District of New Jersey actions: *Merck Sharp & Dohme Corp. v. Par Sterile Products, LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical Holdings, Inc*., Civil Action No. 3:16-cv-00948; *Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited v. Par Pharmaceutical, Inc.*, Civil Action No. 2:15-cv-07580; and *Alcon Pharmaceuticals, Ltd., Alcon Laboratories, Inc., and Alcon Research, Ltd. v. Par Pharmaceutical, Inc*., 3:15-cv-07240.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, its presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, previously submitting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court (*e.g*., by the assertion of claims and counterclaims), and having engaged in systematic and continuous contacts with the State of New Jersey through the

marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including Par products, within this judicial district.

12. This Court also has personal jurisdiction over Defendant by virtue of, *inter alia*, Par's filing of ANDA No. 205742 with the FDA seeking approval to market and sell Par's Product throughout the United States, including to residents of New Jersey and Par's intent to market and sell the Par product, if approved, to residents of this judicial districts.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

14. On August 4, 2015, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '559 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs." At the time of its issue, the '559 patent was assigned to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the '559 patent, which claims methods related to the treatment of urea cycle disorder patients with glyceryl tri-[4-phenylbutyrate] based on measurement of fasting plasma ammonia levels. A true and correct copy of the '559 patent is attached hereto as Exhibit A.

15. On February 9, 2016, the USPTO duly and legally issued the '278 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs." At the time of its issue, the '278 patent was assigned to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the '278 patent, which claims methods related to the treatment of urea cycle disorder patients with glyceryl tri-[4-

phenylbutyrate] based on measurement of fasting plasma ammonia levels. A true and correct copy of the ’278 patent is attached hereto as Exhibit B.

16. On May 3, 2016, the USPTO duly and legally issued the ’966 patent entitled “Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs.” At the time of its issue, the ’966 patent was assigned to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the ’966 patent, which claims methods related to the treatment of urea cycle disorder patients with glyceryl tri-[4-phenylbutyrate] based on measurement of fasting plasma ammonia levels. A true and correct copy of the ’966 patent is attached hereto as Exhibit C.

RAVICTI®

17. Horizon Therapeutics, Inc. is the owner of FDA-approved New Drug Application No. 203284 (“the RAVICTI® NDA”) for glycerol phenylbutyrate oral liquid 1.1gm/ml, which is sold by Horizon Pharma USA, Inc. in the United States under the trademark RAVICTI®.

18. RAVICTI® is currently approved by the FDA for use as a nitrogen-binding agent for chronic management of adult and pediatric patients ≥ 2 years of age with urea cycle disorders that cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

19. Pursuant to 21 U.S.C. § 355, and attendant FDA regulations, the ’559 patent, the ’278 patent, and the ’966 patent are listed in the FDA publication entitled “Approved Drug Products and Therapeutic Equivalence Evaluations,” (“the Orange Book”) for the RAVICTI® NDA.

20. The ’559 patent, the ’278 patent, and the ’966 patent qualify for listing in the Orange Book in connection with NDA No. 203284 because each patent claims an approved use of RAVICTI®.

PAR'S ANDA

21. On information and belief, Par submitted the Par ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market glycerol phenylbutyrate oral liquid. On information and belief, the Par ANDA seeks approval to market the Par Product for use as a nitrogen-binding agent for chronic management of adult and pediatric patients ≥ 2 years of age with urea cycle disorders that cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

22. On information and belief, the conditions of use for which Par seeks approval of the Par Product in the Par ANDA are the same as those set forth in the FDA-approved labeling for RAVICTI®.

23. On information and belief, the Par ANDA refers to and relies upon the RAVICTI® NDA and contains data that, according to Par, demonstrate the bioequivalence of the Par Product and RAVICTI®.

24. Horizon Therapeutics, Inc. received from Par a letter, dated September 14, 2015, stating that Par included a certification in the Par ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV Certification"), that the '559 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Par Product.

25. Horizon Therapeutics, Inc. received from Par a letter, dated March 11, 2016, stating that Par included a Paragraph IV Certification in the Par ANDA that the '278 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Par Product.

26. Horizon Therapeutics, Inc. received from Par a letter, dated June 2, 2016, stating

that Par included a Paragraph IV Certification in the Par ANDA that the '966 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Par Product.

27. The Par ANDA seeks approval to engage in the commercial manufacture, use, offer to sell or sale of the Par Product before the expiration of the '559 patent, the '278 patent, and the '966 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,095,559

28. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-27 of this Complaint.

29. Defendant has infringed the '559 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Par Product prior to the expiration of the '559 patent.

30. Defendant's use, offer to sell, or sale of the Par Product within the United States, during the term of the '559 patent also would infringe the '559 patent under 35 U.S.C. § 271(a), (b) and/or (c).

31. On information and belief, the conditions of use for the Par Product for which Par seeks approval in the Par ANDA fall within one or more of the claims of the '559 patent. If approved, use of the Par Product in accordance with the proposed labeling submitted in the Par ANDA would infringe one or more of the claims of the '559 patent.

32. Upon approval of the Par ANDA, and the commercial marketing thereof, Defendant will actively induce and/or contribute to infringement of the '559 patent.

33. Upon information and belief, Defendant had actual and constructive notice of the

'559 patent prior to filing Par's ANDA, and Defendant's infringement of the '559 patent has been, and continues to be, willful.

34. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA be a date that is not earlier than the expiration of the '559 patent, or any later expiration of any exclusivity or extension of the '559 patent to which Plaintiff or the patent may become entitled.

35. Plaintiff will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '559 patent.

36. Plaintiff has no adequate remedy at law.

37. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 9,254,278

38. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-37 of this Complaint.

39. Defendant has infringed the '278 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Par Product prior to the expiration of the '278 patent.

40. Defendant's use, offer to sell, or sale of the Par Product within the United States, during the term of the '278 patent also would infringe the '278 patent under 35 U.S.C. § 271(a), (b) and/or (c).

41. On information and belief, the conditions of use for the Par Product for which Par seeks approval in the Par ANDA fall within one or more of the claims of the '278 patent. If

approved, use of the Par Product in accordance with the proposed labeling submitted in the Par ANDA would infringe one or more of the claims of the '278 patent.

42. Upon approval of the Par ANDA, and the commercial marketing thereof, Defendant will actively induce and/or contribute to infringement of the '278 patent.

43. Upon information and belief, Defendant had actual and constructive notice of the '278 patent prior to filing Par's ANDA, and Defendant's infringement of the '278 patent has been, and continues to be, willful.

44. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA be a date that is not earlier than the expiration of the '278 patent, or any later expiration of any exclusivity or extension of the '278 patent to which Plaintiff or the patent may become entitled.

45. Plaintiff will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '278 patent.

46. Plaintiff has no adequate remedy at law.

47. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 9,326,966

48. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-47 of this Complaint.

49. Defendant has infringed the '966 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Par Product prior to the expiration of the '966 patent.

50. Defendant's use, offer to sell, or sale of the Par Product within the United States, during the term of the '966 patent also would infringe the '966 patent under 35 U.S.C. § 271(a), (b) and/or (c).

51. On information and belief, the conditions of use for the Par Product for which Par seeks approval in the Par ANDA fall within one or more of the claims of the '966 patent. If approved, use of the Par Product in accordance with the proposed labeling submitted in the Par ANDA would infringe one or more of the claims of the '966 patent.

52. Upon approval of the Par ANDA, and the commercial marketing thereof, Defendant will actively induce and/or contribute to infringement of the '966 patent.

53. Upon information and belief, Defendant had actual and constructive notice of the '966 patent prior to filing Par's ANDA, and Defendant's infringement of the '966 patent has been, and continues to be, willful.

54. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA be a date that is not earlier than the expiration of the '966 patent, or any later expiration of any exclusivity or extension of the '966 patent to which Plaintiff or the patent may become entitled.

55. Plaintiff will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '966 patent.

56. Plaintiff has no adequate remedy at law.

57. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for a judgment in their favor and against Defendant, and respectfully requests the following relief:

A. A judgment declaring that Defendant has infringed one or more claims of U.S. Patent No. 9,095,559;

B. A judgment declaring that Defendant has infringed one or more claims of U.S. Patent No. 9,254,278;

C. A judgment declaring that Defendant has infringed one or more claims of U.S. Patent No. 9,326,966;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendant, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and its successors and assigns, from using, offering to sell, or selling the Par Product within the United States, prior to the expiration date of the ’559 patent;

E. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendant, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and its successors and assigns, from using, offering to sell, or selling the Par Product within the United States, prior to the expiration date of the ’278 patent;

F. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendant, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and its successors and assigns, from using, offering to sell, or

selling the Par Product within the United States, prior to the expiration date of the '966 patent;

G. If Defendant uses, offers to sell, or sells the Par Product within the United States, prior to the expiration of the '559 patent, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

H. If Defendant uses, offers to sell, or sells the Par Product within the United States, prior to the expiration of the '278 patent, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

I. If Defendant uses, offers to sell, or sells the Par Product within the United States, prior to the expiration of the '966 patent, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

J. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Par ANDA shall be a date not earlier than the expiration date of the '559 patent, the '278 patent, and/or the '966 patent, inclusive of any extensions;

K. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

L. Costs and expenses in this action;

M. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

Date: June 30, 2016

s/ John E. Flaherty
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Of Counsel for Plaintiff Horizon Therapeutics, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff Horizon Therapeutics, Inc., by its undersigned attorneys, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy, to the extent that it is directed to allegations of infringement of the '559 patent, is the subject of the following pending action, which involves different defendants and a different ANDA:

- *Horizon Therapeutics, Inc. v. Lupin Ltd. and Lupin Pharmaceuticals Inc.*, Civil Action No. 1:15-cv-07624-RBK-JS (D.N.J.)

Respectfully submitted,

Date: June 30, 2016

s/ John E. Flaherty
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